

Docket No.: 30566/39634

(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Rosanne M. Crooke et al.

Application No.: 10/712,795 Confirmation No.: 6394

Filed: November 13, 2003 Art Unit: 1636

For: ANTISENSE MODULATION OF Examiner: Not Yet Assigned

APOLIPROTEIN B EXPRESSION

## **INFORMATION DISCLOSURE STATEMENT (IDS)**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR §1.56, §1.97 and §1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom. Copies of documents B1 - B4 and C1-C17 have been previously submitted to the Patent Office in U.S. Serial No. 10/147,196, on which the instant application relies for priority. However, copies of these documents will be resubmitted at the Examiner's request.

Copies of documents C18 and C19 are submitted herewith. C18 is the abstract of CD-ROM purportedly contributed to the public collection of the Katherine R. Everett Law Library of the University of North Carolina on March 14, 2001. The CD-ROM is purported to contain a document entitled "On the Preparation and Utilization of Isolated and Purified Oligonucleotides." The document has been included on the form PTO/SB/08A and a paper copy is enclosed herewith. The CD-ROM is also purported to contain a listing of "all sequence of 8 to 12 nucleotides that have between 40 and 60 percent G+C content and are

Application No.: 10/712,795 Docket No.: 30566/39634

free of homopolymeric runs of 4 or more bases and directly or inversely repeated regions of 4 or more basis" a paper copy of which is too voluminous to submit herewith. Applicant's submission of the foregoing information shall not be construed as an admission that the purported CD-ROM contains that which it is purported to contain nor shall it be constructed as an admission that the purported CD-ROM is a publication.

C19 refers to an abstract published in the Federal Register relating to use of oligonucleotides and Apolipoprotein B.

In accordance with 37 CFR §1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR §1.56(a) exists. In accordance with 37 CFR §1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR §1.98 and the Examiner is respectfully requested to consider the listed references.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR §1.97(b)(3)). As such, no fees are believed due in connection with this paper. If fees are found necessary, the Commissioner is hereby authorized to charge any deficiency in the fees filed, to Marshall, Gerstein & Borun Deposit Account No. 13-2855.

Dated: March 31, 2005

Respectfully submitted,

Katherine L. Neville

Registration No.:53,379

MARSHALL, GERSTEIN & BORUN LLP

233 S. Wacker Drive, Suite 6300

**Sears Tower** 

Chicago, Illinois 60606-6357

(312) 474-6300

Agent for Applicants

PTO/SB/08a/b (08-03)

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

1 of 2 Sheet

Complete if Known			
Application Number	10/712,795-Conf. #6394		
Filing Date	November 13, 2003		
First Named Inventor	Rosanne M. Crooke		
Art Unit	1636		
Examiner Name	Not Yet Assigned		
Attorney Docket Number	30566/39634		

			U.S. PA	TENT DOCUMENTS	
Examiner	0:44	Document Number Pr	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where
Initials*	Cite No. <sup>1</sup>	Number-Kind Code <sup>2</sup> ( if known)	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear
	A1	5,220,006-B1	06-15-1993	Ross et al.	
	A2	5,656,612-B1	08-12-1997	Monia	
	A3	5,786,206-B1	07-28-1998	Smith et al.	
	A4	6,096,516-B1	08-01-2000	Kwak et al.	
	A5	6,156,315-B1	12-05-2000	Goldberg et al.	

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.1	Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
i	B1	WO 99/18986-A1	04-23-1999			П	
	B2	EPO-0 911 344	04-28-1999			$\Box$	
	В3	WO 01/12789	02-22-2001				
	B4	WO 01/30354	05-03-2001				

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not \*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \*\*CITE NO.: Those patent(s) or publication(s) which are marked with an double asterisk (\*\*) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached. attached.

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	C1	Boren et al., "A Simple and Efficient Method for Making Site-directed Mutants, Deletions, and Fusions of large DNA Such as P1 and BAC Clones," <i>Genome Research</i> , 1123-1130 (1996).	
	C2	Branch, "A Good Antisense Molecule is Hard to Find," TBS 23:45-50 (1998).	
	СЗ	Davidson et al., "Apolipoprotein B:mRNA Editing, Lipoprotein Assembly, and Presecretory Degradation," <i>Annu. Rev. Nutr. 20</i> : 169-193 (2000).	
	C4	Deeb et al., "Chromosomal localization of the human apoliproptein B gene and detection of homologous RNA in monkey intestine," <i>Proc. Natl Acad. Sci USA 83</i> :419-422 (1986).	
	C5	Farese et al., "Knockout of the mouse apolipoprotein B gene results in embryonic lethality ion homozygotes and protection against diet-induced hypercholesterolemia in heterozygotes," <i>Proc. Natl. Acad. Sci USA 92</i> :1774-1778 (1995).	
	C6	Hajjar et al., "The Role of Lipoprotein(a) In Atherogenesis and Thrombosis," <i>Annu. Rev. Med.</i> 47:423-442 (1996).	
	C7	Innerarity et al., "Familial defective apolipoprotein B-100:Low density lipoproteins with abnormal receptor binding," <i>Proc. Natl. Acad. Sci USA 84</i> :6919-6923 (1987).	
	C8	Katan et al., "Characteristics of Human Hypo- and Hyper- responders to Dietary Cholesterol," American Journal of Epidemiology 125(3):387-399 (1987).	
	C9	Kim et al., "Genetically modified mice for the study of apolipoprotein B,: Journal of Lipid Research 39: 703-723 (1998).	
	C10	Law et al., "Human apolipoprotein B-100: Cloning, analysis of liver mRNA, and assignment of the gene to chromosome 2," <i>Proc. Natl. Acad. Sci. USA 82</i> :8340-8344 (1985).	

Examiner	Date	 _
Signature	Considered	 

PTO/SB/08a/b (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

30566/39634

Attorney Docket Number

Complete if Known Substitute for form 1449A/B/PTO Application Number 10/712,795-Conf. #6394 INFORMATION DISCLOSURE November 13, 2003 Filing Date STATEMENT BY APPLICANT First Named Inventor Rosanne M. Crooke Art Unit 1636 (Use as many sheets as necessary) Examiner Name Not Yet Assigned

2

2

Sheet

of

C11	McCormick et al., "Transgenic Mice Expressing Human ApoB95 and ApoB97," <i>The Journal of Biological Chemistry 272(38)</i> :23616-23622 (1997).	
C12	Nishina et al., "Synthetic low and high fat diets for the study of atheriosclerosis in the mouse," Journal of Lipid Research 31:859-869 (1990).	
C13	Sandkamp et al., "Lipoprotein(a) Is an Independent Risk Factor for Myocardial Infarction at a Young Age," Clin. Chem. 36/1:20-23 (1990).	
C14	Seed et al., "Relation of Serum Lipoprotein(a) Concentration and Apolipoprotein(a) Phenotype to Coronary heart Disease in Patients with Familial Hypercholesterolemia," <i>The New England Journal of Medicine</i> 1494-1498 (1990).	
15	Tang Quidong et al., "The Inhibition of Antisense Oligodeoxynucleotides on the Expression of Apolipoprotein B in Rat Liver Cells," <i>Chinese Journal of Arteriorsclerosis 7(4):</i> 315-318 (1999).	
C16	Veniant et al., "Susceptibility to Atherosclerosis in Mice expressing Exclusively Apolipoprotein B48 or Apolipoprotein B100," <i>J. Clin, Invest</i> 100(1):180-188 (1997).	
C17	Vessby et al., "Diverging effects of Cholestyramine on Apolipoprotein B and Lipoprotein Lp(a)," Atherosclerosis 44:61-71 (1982).	
C18	Chin, Andrew "On the Preparation and Utilization of Isolated and Purified Oligonucleotides."  Document purportedly located on a CD-ROM and contributed to the public collection of the Katherine R. Everett Law Library of the University of North Carolina on March 14, 2002	
C19	Eggerman et al. "Use of Oligonucleotides to Target Nucleic Acid Sequences Encoding Apolipoprotein B to Decrease Serum Apolipoprotein B and Cholesterol Levels" Federal Register Volume 65, Number 110 (2000)	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner	Date	
Signature	 Considered	

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.